



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/560,825

03/13/2006

Gabi Weizman

27128U

7406

20529

7590

03/18/2009

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER

BOCKELMAN, MARK

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,825	Applicant(s) WEIZMAN ET AL.	
	Examiner Mark W. Bockelman	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-19-2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-13,15-26 and 29-52 is/are pending in the application.
- 4a) Of the above claim(s) 29-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13, 15-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-10-8, 7-11-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 29 - 52 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims are subcombinations of the originally examined claims and which would require the examiner to restart the entire search over at the midpoint of the examination process

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29 - 52 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claims 1-2, 4-13, 15-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant appears to be mixing embodiments that were not originally disclosed as useable together. Independent claims 1 and 12 require the use of a protrusion in the restrainer envelope which is used to create a peristaltic type action when using a single balloon/compartment inflatable

Art Unit: 3766

member as shown in figures 1-2c. There appears to be no disclosure with this embodiment regarding how the balloon inflates (i.e. one end before the other) in this embodiment or the use of more than one balloon (see claim language "at least one balloon") as well as dependent claims that recite different compartments.

Notwithstanding there is no discussion as to how a two compartment balloon would be used with a protrusion. Figure 4 on the other hand appears to be an alternative to the prior mentioned species which does not require a protrusion to create a peristaltic action since the first balloon is inflated to shut off flow while the second balloon is used to pump. Thus the embodiments are distinct but the claims now recite portions from each.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-2, 4-6, 8-13, 15-17, 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khaghani et al. USPN 6,984,201, Khaghani et al. WO 02/24254 in view of Hakim USPN 3,675,656.

Referencing the US patent, Khaghani et al. teach a pressure applying device 1 comprising a balloon 10 with optionally two or more balloon compartments (column 9, lines 55-60, column 15 lines 10-11), a restrainer 11 formed as a sleeve (column 8 lines 54-63), a control console comprising an inflation unit 30, an ecg sensor 51, and a control unit 50. Khaghani et al also teaches a sheath 33 (column 12 lines 25-30 Figure

Art Unit: 3766

8). The at least 2 balloon compartments may be independently inflatable (column 15 lines 10-13). The control console may be implantable in a patient (column 9, lines 10-12, column 14, lines 41-42, column 16, lines 57-60) The pressure applying device 1 may be ached around an artery such as the descending aorta (column 13, lines 59-60 Fig. 11). Applicant differs in reciting a protrusion in the envelope. To have provided the restrainer sleeve 16 of Khaghani with a protrusion member of Hakim (element 36) for ensuring complete closure of the vessel would have been obvious. To have made it in to an annular protrusion to accommodate movement of the blood vessel within the sleeve member would have been apparent to those of ordinary skill in the art. One could consider the protrusion of Hakim to be on an upstream portion that extends from the protrusion to one end of the envelope 18 with the remainder of the envelope being the downstream portion. Thus placing the protrusion in the Khaghani envelope either in the middle or upstream would still achieve the same result. The inflation action would be the same as in applicant's figures since the upstream pressure would be greater than the downstream pressure and with the down stream portion of the balloon creating a peristaltic effect as seem in figure 5 of Hakim. The limitations of claims 9-10, 20-21 are read to be intended use statements and not actual structure or method steps. There is no reason that the controller of Khaghani is not capable of being attached to a belt, although prior to an implantation. Thus, the device is considered to be small enough to be carried by the patient (inside the body) and is capable of being attached to a belt. Alternatively if the claims are read more narrowly, the substitution of an external controller carried by a belt on a person would have obvious. Regarding claims 23-24, to

Art Unit: 3766

have merely lowered the positioning of the counterpulsation device down the ascending aorta and to the iliac arteries would have been an obvious alternative location for the device. Applicant's specification provides minimal discussion of such a location and appears to be an after thought with no stated criticality.

Claims 1-2, 4, 7-13, 15,18-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Chiu USPN 5,429,584 alone or alternatively in view of Pacella et al USPN 6,045,496, either further in view of and further in view of Hakim USPN 3,675,656.

Chiu teaches an implantable control console and inflation unit 10 and 54, heart rate sensing means 24, bladder 10 and flow director 54, a sleeve restrainer 16 and a balloon member 52 for compressing the aorta against the sleeve. Applicant's statements of intended use such as where the controller is adapted to be worn are given little to no patentable weight since they impart no meaningful structure and the controller is capable of being worn anywhere. While the sensor of Chiu is unspecified as to the type but stated as a heart rate sensor, because it is considered to detect electrocardiograph signals such as systole and diastole it is considered to meet applicant's claim language. Applicant does not require the sensor to detect electrical signals of the heart, only those signals that are represented on an electrocardiograph. However, in the event such claims are read more narrowly, to have used an ecg detector would have been obvious in view of Pacella. The examiner takes official notice that using blood pressure for detecting heart rate and for verifying an ecg are well known. To have included a blood pressure sensor in the Chiu heart rate sensor would

Art Unit: 3766

have been obvious. Including a sheath attachment member to prevent the balloon member from falling out of the sleeve would have been obvious. To have used the compression member with other arteries such as the iliac to prevent back flow would have been obvious.

Claims 5-6, 16-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Chiu USPN 5,429,584 alone or alternatively in view of Pacella et al USPN 6,045,496, either in view of Hakim, and further in view of Habib USPN 5,372,573.

Applicant differs in reciting multiple balloon compartments. Habib shows such an arrangement for squeezing vessels. To have included such the Chiu compressing device would have been an obvious substitution to complete the same task.

Claims 7, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khaghani et al. USPN 6,984,201 or WO 02/24254 in view of Hakim as taught or further in view of Wang USPN 6,454,697. Applicant differs in reciting a blood pressure sensor in addition to the ecg sensor. To have included a pressure sensor to adjust counter pulsation in the event of blood pressure that is outside of a safety range would have been an obvious inclusion. Wang is cited as an example of maintaining safe blood pressures in an ecg controlled heart assist device.

Response to Arguments

Applicant's arguments filed 12-19-2008 have been fully considered but they are not persuasive. Upon further consideration, the examiner concludes that in modifying the Khaghani or Chiu references in a manner as shown by Hakim, the applicant's recited pumping effect would be an inherent property of the combination. Notwithstanding, applicant's claims are not supported by their specification as noted above.

Conclusion

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3766

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/
Primary Examiner, Art Unit 3766
March 16, 2009